UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, *ex. rel.* CAMPIE *et al.*,

Plaintiffs,

v.

GILEAD SCIENCES, INC., *et al.*,

Defendants.
_____/

No. C-11-0941 EMC

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

(Docket No. 58)

I. INTRODUCTION

Pending before the Court is Defendants Gilead Sciences, Inc. and Gilead Sciences ULC's (collectively "Gilead") motion to dismiss Relators Jeff Campie and Sherilyn Campie's ("Relators") first amended complaint ("FAC") for failure to state a claim. Docket No. 58. Relators are current and former employees of Gilead. Gilead is a pharmaceutical company who, *inter alia*, supplies federal and state sponsored Medicaid and Medicare programs with drugs for the treatment of HIV/AIDS, cystic fibrosis, and hepatitis, among other serious illnesses. The first amended complaint alleges that Relators discovered, and reported to Gilead officials, numerous serious violations of Federal Food and Drug Administration ("FDA") regulations. Relators allege that Gilead failed to correct these violations, but rather concealed them and that the resulting sale of misbranded, adulterated drugs render each sale of the affected drugs "false" for purposes of the federal False Claims Act and related state laws. Relators further allege that Gilead retaliated against Relator Jeff Campie for his reporting the various FDA violations. Gilead has moved to dismiss Relators' FAC in full. For the foregoing reasons, Gilead's motion will be **GRANTED**, but Relators will be afforded leave to amend.

II. FACTUAL & PROCEDURAL BACKGROUND

A. Parties

Plaintiff-Relator Jeff-Campie is a former Senior Director of Global Quality Assurance for Defendant Gilead Sciences, Inc. FAC ¶ 5. Mr. Campie was employed by Gilead between 2006 and mid-2009. *Id.* While employed with Gilead, Mr. Campie had quality control oversight of (1) all commercially released drug products released by Gilead; (2) Gilead's polices, practices and Good Manufacturing Practices ("GMP") compliance; and (3) the development of quality systems. *Id.* Plaintiff-Relator Sherilyn Campie began working for Gilead in March 2007 as a Senior Research Associate. *Id.* ¶ 6. She still works for Gilead and is Associate Manager, Quality Control where she oversees the stability program for drug products in development in clinical phase trials. *Id.*

Defendant Gilead is a California corporation that develops, manufacturers, promotes, and sells prescription drugs, with a focus on drug products for patients with life threatening diseases, such as HIV/AIDS, Hepatitis, cystic fibrosis, and cardio-pulmonary conditions. *Id.* ¶ 12. Gilead contracts with numerous companies for the manufacture of "active pharmaceutical ingredients" ("APIs") and other products that go into the pharmaceutical products Gilead manufactures and sells. *Id.* The majority of prescriptions for Gilead's drugs are paid for by the federal and state governments through the various health care programs. *Id.*

B. Summary of Relators' Allegations Regarding Gilead's Alleged FDA Violations

Notwithstanding Federal Rule of Civil Procedure 8's command that a complaint contain only a "short and plain statement of the claim," Relators' FAC is a sprawling 191 page, 747 paragraph document that consists largely of a laundry list of alleged FDA violations in immense detail. *See* Fed. R. Civ. P. 8(a). Given the nature of Gilead's challenge to the FAC, the Court need not walk through all of the alleged FDA violations in detail. Rather, the Court provides the following examples of Relators' allegations.

1. Alleged Use of Unregistered Manufacturing Facilities

Relators allege that in or around 2008, Gilead contracted with Synthetics China, LTD to manufacture the API "emtricitabine," (commonly known as "FTC"). *Id.* ¶ 51. FTC is the active ingredient in many of Gilead's HIV/AIDs drugs, such as Emtriva, Truvada, and Atripla as well as

several clinical trial drugs. *Id.* Synthetics China produced FTC at roughly half the cost as Gilead's existing suppliers and Gilead allegedly began using Synthetics China to save money and to trigger price reduction clauses in contracts with other FTC suppliers. *Id.* Gilead ultimately received approval from the FDA to use Synthetics China as an API manufacturer, but according to Relators, Gilead had been including products from Synthetics China in its finished drug products for at least two years before this approval was obtained. *Id.* ¶ 53.

Relators also allege that Gilead falsified or concealed data in support of its application to use Synthetics China as an API manufacturer. For example, in this application, Gilead claimed that it had received three full-commercial-scale batches of FTC from Synthetics China that had passed testing and were consistent with/equivalent to FTC batches made from existing manufacturers. *Id.* Relators contend that this representation was false and that two of the three batches had failed internal testing. *Id.* ¶ 57. One of the batches purportedly contained "residual solvent levels in excess of established limits" and other impurities. *Id.* A second batch had "microbial contamination" and showed the presence of "arsenic, chromium and nickel contaminants." *Id.* Relators allege, nonetheless, that this batch was released for final drug processing and commercial sale. *Id.* Despite being aware of manufacturing problems at Synthetics China, Gilead allegedly released 77 lots of FTC produced by Synthetics China to its contract manufacturers well before FDA approval of the Synthetics China facility. *Id.* ¶ 62, 65.

Relators allege that Gilead actively concealed its use of FTC produced by Synthetics China in a number of ways. First, Gilead imported the FTC at issue through its Canadian facilities (Gilead Alberta) and represented through fraudulent labeling that it was "API supporting Investigational New Drug . . . activities" rather than its true use – API for commercial sales. *Id.* ¶ 70. Second the labels and paperwork for the API was obscured/augmented by the Gilead Alberta shipping paperwork to conceal where the FTC was actually produced. *Id.* ¶ 71. Third, Gilead credited its approved FTC manufacturer Yuhan with the production of the FTC – rather than the true producer, Synthetics China. *Id.* ¶ 72. During this time, Yuhan actually produced no FTC. *Id.*

Relators contend that Gilead's false and misleading statements made in connection with the application to use Synthetics China as an API manufacturer – specifically, failing to disclose its

prior use of Synthetics China and its labeling fraud – "infects each and every batch of final drug product in which Synthetics China's API was included" and thus makes every sale of such final drug to federal or state governments a violation of the False Claims Act and related state laws. *Id.* ¶¶ 76, 77.

Similar to the allegations regarding Synthetics China, Relators allege that Gilead used its Gilead Alberta facilities to produce the API ambrisentan two years before the Gilead Alberta facilities were approved by the FDA. *Id.* ¶ 78. Gilead was aware of quality issues with the API produced in this facility – including through patients complaints – but "revised" purity values in the applicable Certificate of Analysis ("COA") to hide these issues. *Id.* ¶¶ 98, 99, 101. Relators contend that every sale by Gilead to a government that incorporated ambrisentan manufactured at Gilead Alberta prior to FDA approval violated the False Claims Act and related state law.

2. Adulteration or Contamination in Gilead's Commercial Drug Products

Relators' FAC alleges numerous instances of Gilead API or final drug products used in commercial sales being adulterated or contaminated. The following are two examples emblematic of Gilead's conduct as alleged by Relators.

a. Allegations Regarding FTC Contamination

As mentioned above, FTC is the API used in Gilead's drugs branded as Emtriva, Truvada, and Atripla (as well as combination drugs based on these three products). *Id.* ¶ 105. Prior to these drugs being approved, Gilead submitted New Drug Applications ("NDA") which listed FTC as an active ingredient and also listed a number of inactive ingredients. *Id.* ¶ 107. The FDA requires that every batch of final drug product contain identical active and inactive ingredients as those listed in the NDA. *Id.* Were a subsequent batch to contain ingredients not listed in the NDA, that product would be "misbranded" in violation of federal law. *Id.* For this reason, Relators contend that the sale of contaminated or adulterated drugs violate federal law. The FAC contains allegations of a number of instances of Gilead's FTC being contaminated.

For instance, Relators contend that Gilead was aware of an impurity known as "cyclic-FTU" that manifested in FTC when FTC was exposed to elevated humidity or temperatures. *Id.* ¶ 109, 110. Starting in mid-2003, Gilead began to observe "black specks" (or "charred and degraded

particles") in its FTC. *Id.* ¶ 110. Relators allege that Gilead failed to disclose the presence of cyclic-FTU – or the fact that its FTC were failing internal testing – to the FDA. *Id.* ¶¶ 113, 114. They further contend that Gilead failed to "assess the long-term health consequences of the contamination and failed to establish a testing method for measuring the level of cyclic-FTU impurities." *Id.* ¶ 118. Relators thus allege that by no later than 2003, most if not all of the FTC batches used to manufacturer Gilead's drug products were "adulterated" with a variety of unapproved contaminants, including cyclic FTU. *Id.* ¶ 112. Despite the fact that the affected FTC lots were adulterated and had failed potency and purity testing, Relators contend that Gilead approved them for use in manufacture without further investigation, considering the black specks to be no more than aesthetic defects. *Id.* ¶ 122-23, 26. While Gilead finally fully disclosed the cyclic-FTU contamination to the FDA in 2010,[1] *id.* ¶ 128, Relators allege that Gilead assured the FDA, that "no field alert report or recall was warranted" despite the fact that the presence of cyclic-FTU altered the chemical composition of its products and no changes had been made to its manufacturing processes to fix the issue. *Id.* ¶ 129.

Similarly, in 2010, Relator Sherilyn Campie allegedly observed three "unknown impurities" in additional FTC lots, and yet Gilead instructed its technicians to ignore the impurities. *Id.* ¶ 132. As a result, they were never identified, quantified, or reported to the FDA. *Id.* ¶ 135. Further, Relators allege that in November 2011, Gilead became aware that FTC lots used to validate Synthetic China's new, larger facility (known as "Plant 203") were "grossly contaminated" with "pinkish-orange particles," brown paper strips, blue colored glass, cement and fibrous building materials, and metal shards. *Id.* ¶¶ 156, 160. Relators allege that at least two of the validation lots from Plant 203 had already been released in the United States for commercial sale. *Id.* ¶ 154. While Gilead allegedly issued an "FDA field alert" about these lots, they "did not make any effort to recall them." *Id.* ¶ 155. Gilead began sieving and reprocessing those lots of contaminated API which it

[1] Relators appear to allege that Gilead at least partially disclosed the presence of "degradation product(s)" had been observed in one of its products in 2005. *Id.* ¶ 118. However, they contend that Gilead falsely represented the impurity was only seen when the drugs were stored in elevated temperature conditions. *Id.* In fact, the impurity had been observed in drugs even stored in normal temperature conditions. *Id.*

still had from the Synthetics China plant in question, resulting in kilograms of material being filtered. *Id.* ¶ 161. The API was then utilized in commercial production – Relators allege that Gilead failed to destroy any of the API after sieving. *Id.* ¶ 162. Relators further allege that Gilead took steps to alter the affected API's identification numbers to "give the appearance that they originated at the Gilead Alberta facility rather than the Synthetics China location under scrutiny." *Id.* ¶ 163.

Relators assert in their FAC that all of the NDAs for drugs which incorporate FTC contained "false statements and material omissions, in that they listed ingredients" that did not include cyclic-FTU, methylene-bridged impurities, or the other impurities and contaminants as referenced throughout the complaint. *Id.* ¶ 138. They allege that had the FDA known of these false statements and material omissions (or had it been aware of the adulteration), the FDA would not have approved the drugs or would have withdrawn approval. *Id.* ¶ 140. Relators further assert that the sale of the drugs containing the contaminated FTC would have been illegal under federal law as the drugs were "misbranded." *Id.* ¶ 144. Accordingly, Relators assert that all claims presented to the federal or state governments are "false claims" in violation of the False Claims Act and related state law claims. *Id.* ¶ 142.

Similarly, the Relators contend that Gilead certified in its certificate of analysis ("COA")[2] for drugs which incorporated the Plant 203-produced FTC that the API was "in compliance with cGMP [current good manufacturing practice] and manufactured according to specifications in the NDA." *Id.* ¶ 174. However, as discussed above, it is alleged that Gilead knew this FTC was, in fact, contaminated by 2011. *Id.* They allege that had the FDA been notified of these false and material statements in the COA, it would not have approved Plant 203, or would have withdrawn approval. *Id.* ¶ 175. Accordingly, relators contend that all sales of drugs containing FTC from Plant 203 were "false claims" within the meaning of the False Claims Act and related state law claims. *Id.* ¶ 176.

[2]According to the complaint, "[f]or every released batch of API or finished drug product, manufacturers are required to create a Certificate of Analysis ("COA") certifying that the batch was manufactured according to the specifications contained either in an Investigational New Drug ("IND") application or in a New Drug Application ("NDA")." FAC ¶ 32.

b. Allegations Regarding TDF Contamination

In April 2001, Gilead submitted an NDA to the FDA for approval of its drug "Viread" – a drug used to treat HIV and Hepatitis B. *Id.* ¶ 179. The FDA approved Viread for commercial sale and clinical use in October 2011. *Id.* The active ingredient of Viread is tenofovir disoproxil fumarate ("TDF"). *Id.* ¶ 181.

While the NDA for Viread was pending, Gilead was aware that black particles had been discovered in numerous Viread tablets manufactured at by its contractor Patheon. *Id.* ¶ 180. These batches showed "clear adulteration and contamination" insofar as none of the active or inactive ingredients was black – TDF is a "white to off-white crystalline powder." *Id.* ¶ 181. Later testing eventually showed that the specks in question consisted of teflon, charred TDF, acetaminophen, metal shavings, and other materials. *Id.* ¶ 185. Gilead used the contaminated TDF lots to validate its NDA submission for Viread and eventually sold the affected Viread tablets into the commercial market without ever disclosing the existence of the black particles. *Id.* ¶ 180, 184. Affected lots of TDF were also incorporated into validation batches of Gilead's drug Truvada and Atripla that were produced in connection with the filing of the NDAs for those drugs. *Id.* ¶ 187.

Gilead allegedly justified internally its failure to disclose the black particles to the FDA (or to list them as additional ingredients) by referring to them as "aesthetic defects." *Id.* ¶ 188. In 2008, Relator Jeff Campie had an independent forensic lab analyze samples from 8 batches of commercially released Viread and Truvada tablets which showed black particles in the tablets. *Id.* ¶ 191. The results showed that one particle was steel swarf, another particle was identified as steel wire, and the remaining particles were "composed of chromium nickel, stainless steel, titanium, chromium, iron, and cobalt." *Id.* ¶ 192. Despite the result of this test, Gilead found that the black particles occurred at a sufficiently low frequency so as to constitute only an "aesthetic defect." *Id.* ¶ 193. Relators allege that in September 2010, the FDA issued a warning letter to Gilead regarding visible contaminants in the company's drugs manufactured in one of Gilead's facilities. *Id.* ¶ 194.

Relators contend that because Gilead's NDAs for drugs using TDF did not list the black specks as an "ingredient," (1) the NDAs were false and fraudulent; (2) the FDA would not have approved the drugs (or would have withdrawn its approval) had it known about them, and therefore

all claims presented to federal and state government relating to these drugs constitute "false claims." *Id.* ¶ 199.

3. Adulteration or Contamination in Gilead's Clinical Drug Products

In addition to the above contamination issues involving Gilead's commercially sold drugs, Relators allege a number of instances of contamination in Gilead's drug products used in clinical trials. The following are two examples.

a. Contamination in Viread Used During Pediatric Clinical Trials

As part of its approval of Viread, the FDA required that Gilead conduct clinical trials regarding the efficacy of Viread and TDF on pediatric patients infected with HIV. *Id.* ¶ 248. Beginning in 2002, Gilead began conducting this clinical trial. *Id.* ¶ 250. During the clinical trial, Relators contend that the Viread was made with TDF that contained "black particles, foreign matter, gross contamination, and visible filth" from unknown origins. *Id.* Gilead never reported this to the FDA, and instead certified the results of multiple studies. *Id.* Relators contend that Gilead was motivated to ensure that it obtain an NDA for pediatric use of Viread as well as a 6 month extension of patent exclusivity on the TDF molecule from the FDA (worth approximately $3 billion in sales). *Id.* ¶ 270.

The "black and brown specks" were first observed in several lots of TDF in November 2002. *Id.* ¶ 252. Even though Gilead was unable to locate the source of the particles or how it was introduced into the manufacturing process, it nevertheless decided to go forward with manufacturing and only instructed its contractor to continue "appearance inspections" and sampling. *Id.* Eventually, Gilead suspended even these superficial inspections and sampling. *Id.* ¶ 254. TDF lots containing these contaminants were used in a number of clinical trials, such as a Phase III trial entitled "Safety and Efficacy of Switching from Savudine or Zidovudine to Tenofovir DF in HIV-1 infected children." *Id.* ¶ 257. The TDF lots used in this study were, according to internal chemistry memos, contaminated with "small black and reddish-brown particles" that Gilead believed to probably (though not definitively) be Teflon. *Id.* ¶ 258. Gilead concluded the particles were "cosmetic defects" that had no impact on the efficacy of the drug. *Id.* ¶ 259. Later testing of TDF manufactured from a contractor showed that the TDF API in this lot was also contaminated with

acetaminophen ("APAP") – a drug that Eurand manufacturers in the same facility. *Id.* ¶ 262, 263. This lot was released for clinical use in July 2008. *Id.* ¶ 269.

Relators allege that Gilead never notified the FDA of the contamination issues (either the black/brown specks, the presence of Teflon, or the presence of APAP) and in January 2012, the FDA approved the NDA for pediatric use of Viread. *Id.* ¶ 272. Relators contend that had the FDA known of these issues, it would not have approved the drug formulation. *Id.* ¶ 275. Because of this, and because the presence of the contaminants rendered the Viread misbranded, Relators contend that any claims made to the federal or state governments regarding this drug are "false claims." *Id.* ¶¶ 277, 279.

b. Contaminated Hepsera Used in Pediatric Clinical Trial

As part of its approval of Hepsera, the FDA required Gilead to develop and conduct clinical trials for a pediatric formulation of its drug Hepsera for pediatric patients infected with Hepatitis B. *Id.* ¶ 281. During the clinical trial, Relators allege that Gilead utilized Hepsera containing the API adefovir dipivoxil ("adefovir DP") that failed stability testing regarding potency and purity. They also allege that the placebos employed during the test had gross contamination, visible filth, and cadmium from unknown origins. *Id.* ¶¶ 282, 283. In addition, samples of adefovir DP from a lot produced in September 2002 began to fail internal testing for potency (76 %) and the presence of impurities (20%). *Id.* ¶ 288. Nonetheless, Gilead concluded the failed tests did not reflect on the suitability of the adefovir DP lot, simply terminated the internal testing condition, never reported the failed test results, and continued to use the adulterated lot in the clinical study. *Id.* ¶ 289.

At the same time as the above, Relators allege that foreign matter was also observed in a placebo batch used during the clinical study. *Id.* ¶ 290. Forensic testing of the affected batch revealed that the sample contained cadmium – a "critical" defect based on Gilead's internal classification. *Id.* ¶ 292. Nonetheless, Gilead did not reject and dispose of the batch, but rather released the placebo to the clinical study, labeling the contamination as "isolated" with "no conclusive evidence to pinpoint the source of the particle." *Id.* ¶ 295. Gilead never notified the FDA of the contaminated placebo used in the pediatric clinical trial. *Id.* ¶ 296.

Relators contend that had the FDA known about the impurities and contaminations in the Hepsera and placebo, it would not have approved the pediatric formulation of Hepsera. *Id.* ¶ 299. This, plus the fact the Hepsera was allegedly misbranded render any claims filed with the federal and state government for this drug to be "false claims.' *Id.* ¶¶ 301, 303.

III. DISCUSSION

A. Legal Standard

Under Rule 12(b)(6), a party may move to dismiss based on the failure to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). A motion to dismiss based on Rule 12(b)(6) challenges the legal sufficiency of the claims alleged. *See Parks Sch. Of Bus. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). In considering such a motion, a court must take all allegations of material fact as true and construe them in the light most favorable to the nonmoving party, although "conclusory allegations of law and unwarranted inferences are insufficient to avoid a Rule 12(b)(6) dismissal." *Cousins v. Lockyer*, 568 F.3d 1063, 1067 (9th Cir. 2009). A claim must meet the standard addressed in Rule 8, and include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "Under the pleading requirements of Federal Rule of Civil Procedure 8, [a court] must determine whether the complaint contains 'sufficient factual matter' that, taken as true, 'state a claim for relief [that] is plausible on its face.'" *United States ex rel. Lee v. Corinthian Colleges*, 655 F.3d 984, 991 (9th Cir. 2011) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009)).

Additionally, when alleging fraud or mistake, a relator is held to a heightened pleading standard, and is required to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Because they involve allegations of fraud, *qui tam* actions under the FCA must meet not only the requirements of Rule 8, but also the particularity requirements of Rule 9. *Corinthian Colleges*, 655 F.3d at 992. Notably, Rule 9(b) requires only that the circumstances of fraud be stated with particularity; other facts may be pled generally, or in accordance with Rule 8. *Id.* The Ninth Circuit has joined the Fifth Circuit in concluding, in accord with the general pleading requirements under Rule 9(b), that it is sufficient to allege, "particular details of a scheme to submit

false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Ebeid ex rel. U.S. v. Lungwitz*, 161 F.3d 993, 998-999 (9th Cir. 2010).

A relator must provide enough detail to give the defendant notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong. *Id.* The relator must also supply reasonable indicia that false claims were actually submitted. *Id.* The complaint must refer to the statute, rule, regulation, or contract that conditions payment on compliance with FDA regulations of drug production. *Id.* at 1000. Under Rule 9(b), allegations must include details and facts setting out the who, what, when, where, and how. *Id.*

B. Gilead's Motion to Dismiss Relators' Federal False Claims Act Will Be Granted

As relevant to this action, the False Claims Act ("FCA") provides:

> (a) Liability for certain acts. –
>
> (1) In general. – Subject to paragraph (2), any person who –
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000 . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a). An FCA claim requires a showing of a (1) false statement or fraudulent course of conduct, (2) made with requisite scienter, (3) that was material, and (4) caused the government to pay out money or forfeit moneys due. *See U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006).

Congress designed the FCA to "broadly . . . protect the funds and property of the government" by preventing and punishing false or fraudulent conduct. *Rainwater v. United States*, 356 U.S. 590, 582 (1958); *see also United States v. Bornstein*, 423 U.S. 303, 309 n.5 (1976) ("According to its sponsor, the False Claims Act was adopted 'for the purpose of punishing and preventing . . . frauds.'"). The FCA is "intended to reach all types of fraud, without qualification,

that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). At the same time, however, the FCA is not a catchall anti-fraud provision – it "'attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment.'" *Cafasso, U.S. ex. rel. v. General Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)).

Gilead has moved to dismiss Relators' FCA claim, contending that Relators' allegations that Gilead committed various FDA regulatory violations fail, as a matter of law, to state a viable FCA action. Docket No. 58, at 7. They argue that at no point during the Medicare or Medicaid reimbursement process did Gilead certify (expressly or impliedly) that it had complied with FDA safety or GMP regulations. Accordingly, it contends there was no false or fraudulent statement made in connection with the request for reimbursement.

Relators respond that Gilead's alleged misconduct gives rise to an actionable FCA claim under three separate theories. Relators' first two theories assert that the reimbursement claims at issue in this case were "legally false" in that they were "tainted by some *underlying* statutory, regulatory, or contractual violation made in connection with [those] claim[s], which renders the claim[s] ineligible for reimbursement." *U.S. ex. rel. Kester v. Novartis Pharms. Corp.*, — F. Supp. 2d — , 2014 WL 4230386, at *4 (S.D.N.Y. Aug. 7, 2014) (emphasis added). First, Relators assert that the claims at issue are false insofar as Gilead falsified information to the FDA, misrepresenting to the FDA compliance with FDA regulations at "virtually every stage of the supply-chain process." Docket No. 84, at 15. Second, Relators contend that they have stated a claim under a promissory fraud or "fraud-in-the-inducement" theory insofar as Gilead's fraudulent activity was used to obtain a federal benefit – namely, FDA approval of their drugs which was, in turn, used to get their drugs covered under Medicare and Medicaid (a prerequisite to payment). *Id.* Relators' final theory is one of factual falsity – asserting that Gilead knowingly supplied nonconforming drugs and misrepresented their quality to purchasers (who ultimately sought reimbursement from the government under Medicare and Medicaid). Docket No. 84, at 14-15.

1. Relators' False Certification and Promissory Fraud Theories Fail Because the Alleged Fraud Was Directed at the FDA, not the Centers for Medicare and Medicaid, the Payor Agency, Distinct from the Reimbursement Process

As detailed above, the FAC in this action contains sprawling allegations contending that Gilead has engaged in a widespread pattern of violating safety and GMP statutes and regulations promulgated (and enforced) by the FDA. However, the fact that Gilead may have knowingly violated these statutes and regulations, without more, does not suffice to state a FCA claim. "Violations of laws, rules, or regulations alone do not create a cause of action under the FCA." *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996). Rather, it is the "false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit." *Id.* And, as discussed below, the FCA requires that false certification (*i.e.*, the false statement within the meaning of the FCA) be directed to the government as part of the reimbursement process. In the case at bar, the FDA was not the payor agency and was not directly involved in the reimbursement process.

False certifications[3] come in two varieties – express and implied – and either may form the basis of FCA liability. "Express certification" occurs when an "entity seeking payment certifies compliance with a law, rule or regulation as part of the process through which the claim for payment is submitted." *Ebeid*, 616 F.3d at 998. By comparison, "[i]mplied false certification occurs when an entity has previously undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim." *Id.; see also United States v. Empire Educ. Corp.*, 956 F. Supp. 2d 248, 255 (N.D.N.Y. 2013) ("[A]lthough the claim for payment does not certify compliance with a statute or regulation on its face, compliance is a prerequisite to payment under the express statutory or regulatory terms."). To prove materiality under either theory Relators

[3] The term "certification" in this context does not carry with it any talismanic significance, but is "simply another way of describing a false statement made to the government." *Gonzalez v. Planned Parenthood of L.A.*, No. CV 05-8818 AHM (FMOx), 2012 WL 2412080, at *4 (C.D. Cal. June 26, 2012); *see also U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006) (rejecting view that the"word 'certification' has some paramount and talismanic significance").

must demonstrate that the certification and compliance with the statutory, regulatory, or contractual provision was a "prerequisite to obtaining a government benefit" or the "*sine qua non* of receipt of state funding." *Ebeid*, 616 F.3d at 998 (quoting *Hopper*, 91 F.3d at 1266).

In addition to the false certification theory of liability, the Ninth Circuit has recognized FCA liability based on promissory fraud or "fraud-in-the-inducement." Under this theory, no false statement regarding compliance with government regulations is needed, but rather, "liability will attach to each claim submitted to the government under a contract, when the contract or extension of government benefit was originally obtained through false statements or fraudulent conduct." *U.S. ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166, 1173 (9th Cir. 2006). The Ninth Circuit has noted that this theory is "not so different from the false certification theory, and even requires the same elements." *Id.* at 1174.

Relators have failed to state a claim under the FCA under either a false certification or promissory fraud theory. Fundamentally, they have failed to allege that Gilead engaged in any fraudulent conduct or made any false statement to the Centers for Medicare and Medicaid Services ("CMS") – the governmental agency that administers reimbursement under the Medicare and Medicaid regimes – as part of a request for payment. *See Gundersen Luterhan Med. Ctr., Inc. v. Johnson*, No. 06-2195 TFH/DAR, 2009 WL 596974, at *1 (D.D.C. 2009). In fact, at the hearing, Relators conceded that Gilead had not made any "direct misrepresentation to the payor." Transcript of October 21, 2014 Hearing at 44:1-3 (Docket No. 111). What Relators have alleged, instead, is that Gilead (1) falsely certified to the FDA during the drug approval process that it would comply with GMP regulations while, at the same time, knowingly flouting those regulations and (2) withheld or falsified information and test results in various submissions to the FDA. The Court finds that false certifications, statements, or other fraudulent conduct directed at the FDA during the approval process do not render subsequent Medicare or Medicaid reimbursement requests made to CMS "false" under the FCA. Based on the plain text of the FCA and Ninth Circuit authority interpreting that language, the Court concludes that Relators have failed to state an FCA claim by failing to allege a false claim was made to CMS "for payment."

The FCA imposes liability on an individual who "knowingly presents, or causes to be presented, a false or fraudulent claim *for payment or approval*." 31 U.S.C. § 3729(a)(1) (emphasis added). No circuit court, including the Ninth Circuit, has ever interpreted this statutory language as encompassing a false or fraudulent statement to a licensing or regulatory agency – disconnected from the request for payment – simply because that false or fraudulent statement to that licensing agency ultimately enabled the defendant to achieve eligibility for funding from the payor agency.

"Not every instance in which a false representation of compliance with a regulatory regime is made will lead to liability." *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 114 (2d Cir. 2010), *rev'd on other grounds* 131 S. Ct. 1885 (2011). "The language of [the FCA] plainly links [a defendant's] wrongful activity to the government's *decision to pay*." *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001) (emphasis added); *see also* 31 U.S.C. § 3729(a)(1) (covering any person who "knowingly presents, or causes to be represented, a false or fraudulent claim *for payment*" (emphasis added)). Accordingly, a "false certification of compliance with a statute or regulation cannot serve as the basis for a *qui tam* action under the FCA unless payment is conditioned on that certification." *U.S. ex rel. Siewick v. Jamieson Science & Engineering, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000). Stated another way, "[t]here is no liability under [the FCA] for a false statement unless it is used to get [a] false claim paid." *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 675 (5th Cir. 2003) (en banc).

The Ninth Circuit has recognized this principle by holding that FCA liability "cannot attach 'where regulatory compliance was not a *sine qua non* of receipt of state funding" and the statute at issue did "'not require funding recipients to certify their compliance with federal law and regulations.'" *Ebeid*, 616 F.3d at 997 (quoting *Hopper*, 91 F.3d at 1266). There must be a direct and immediate link between a false statement or fraudulent conduct and the resulting request for payment; payment must be conditioned on the falsity. *Cf. Allison Engine Co. Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672 (2008) (noting that the "direct link between the false statement and the Government's decision to pay or approve a false claim is too attenuated to establish liability" where a defendant makes a false statement without "intend[ing] the Government to rely on that false statement as a *condition of payment*" (emphasis added)).

The Ninth Circuit's decisions in *Hendow* and *Ebeid* provide useful examples of the type of direct link required between the alleged fraudulent conduct or statement and the request for payment. *Hendow* (an express certification case) involved federal subsidies under Title IV and the Higher Education Act. *Hendow*, 461 F.3d at 1168. The applicable statute and regulation at issue in conditioned a school's participation in the subsidy program on having the school enter into an agreement with the Department of Education in which the school agreed to "abide by a panoply of statutory, regulatory, and contractual requirements" – including a ban on the school paying recruiters incentive payments on a per-student basis. *Id.* The defendant – the University of Phoenix – was alleged to have repeatedly certified to the Department of Education that it was in compliance with this incentive ban while intentionally and knowingly violating the ban. *Id.* The Court found these false certifications – *made to the payor agency and entered into for the sole purpose of participating in a federal subsidy program* – were sufficient to establish FCA liability because the "statute, regulation and agreement [there] all explicitly condition[ed] participation and payment on compliance with, among other things, the precise requirement that relators alleged that the University knowingly disregarded." *Id.* at 1167.

Similarly, in *Ebeid* (an implied certification case), the Ninth Circuit distinguished between statutes and regulations which could form the basis of an implied certification theory and those which could not. *Ebeid* involved a defendant health care provider who allegedly engaged in the unlawful corporate practice of medicine and made unlawful referrals to businesses in which the defendant had a "financial interest" in violation of the Stark Act, 42 U.S.C. § 1395nn(a)(1). *Ebeid*, 616 F.3d at 995. The Ninth Circuit concluded that the defendant's alleged "unlawful corporate practice of medicine" could not form the basis of FCA liability because the relator had failed to "refer to any statute, rule, regulation, or contract that conditions payment on compliance with state law governing the corporate practice of medicine." *Id.* at 1000. As to the alleged violations of the Stark Act, however, the court found that the violations could "provide a valid basis from which to imply certification, because [the Act] expressly conditions payment on compliance." *Id.*; *see also* 42 U.S.C. § 1395nn(g)(1) ("No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (a)(1) of this section."). *Ebeid*, therefore,

involved allegations of an implicit certification that was directly tied by the applicable statutory language to the participation in a federal funding program and requests for payment. Because the Stark Act conditioned payment on compliance with the "financial interest" referral bar, every payment submitted to the paying agency by the defendant falsely implied certification of compliance with that bar.

In both *Hendow* and *Ebeid* the false statement or fraudulent conduct was made to an entity administering a federal funding program and as part of the process of obtaining payment from the government. In short, false claims were made "for payment." In contrast, Gilead's non-disclosures and misrepresentations were made to the FDA during the FDA approval process; this process preceded and was distinct to the subsequent reimbursement requests to CMS under Medicare or Medicaid. In short, the misrepresentations at issue were to the FDA, not the payor agency (CMS) and were not made as a condition of reimbursement by CMS. Unlike *Ebeid*, Relators here have not pointed to any law, regulation, or contract provision that conditions CMS's payment on Gilead's compliance with FDA quality assurance rules. Rather, payment is conditioned only on FDA approval of the drugs sold. Here, Gilead had obtained FDA approval of all the drugs in question.

Relators rely heavily on the *Hendow* court's statement that "'[i]f a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork.'" *Hendow*, 461 F.3d at 1168 (quoting *U.S. ex rel. Main v. Oakland City University*, 426 F.3d 914, 916 (7th Cir. 2005)). Relators argue that approval of the drugs by the FDA was part of the causal chain which enabled Gilead ultimately to obtain reimbursement from CMS. However, *Hendow* (and the Seventh Circuit case it quoted) were dealing with a payment process that was separated into discrete steps requiring the submission of different applications. In context, the quote on which Relators rely stands for the proposition that a defendant cannot escape FCA liability for false statements made to the payor agency simply because that agency divided the process into multiple stages. It does not stand for the proposition that a falsehood told to a governmental regulatory agency can form the basis of FCA liability simply because the fraudulently induced action of that agency was part of a causal chain that ultimately led to eligibility for payment from the payor agency. Such causation is insufficient to state a claim

under the FCA. *Cf. U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) (adopting a proximate causation standard "to determine whether there is a sufficient nexus between the conduct of the party and the ultimate presentation of the false claim to support liability under the FCA"). Nothing in *Hendow* eliminates the requirement under the FCA that the alleged fraud be made as part of a claim for payment to the payor agency.[4]

Relators cite two district court cases where a misrepresentation to a third party in a "licensing role" was held to state a viable theory for FCA liability because of a subsequent request for payment made to a separate, payor agency. *See, e.g.*, *Amphastar Pharms. Inc. v. Aventis Pharma SA*, No. EDCV-09-0023 MJG, 2012 WL 5512466 (C.D. Cal. Nov. 14, 2012) (finding allegations that an entity, *inter alia*, made false representations to the PTO and FDA sufficient to allege a false or fraudulent request for payment); *United States v. Chapman University*, No. SACV 04-1245 JVSRCX, 2006 WL 1562231 (C.D. Cal. May 23, 2006) (finding FCA liability where defendant certified they would comply with applicable statutes and regulations, one of which requiring accreditation by a third party entity, and the defendant allegedly obtained the required accreditation through fraud). For the reasons discussed above, the Court finds these district court decisions unpersuasive and unsupported by the language of the FCA and circuit court precedent. Furthermore, such an expansive reading of the FCA would lead to perverse results. For example, under these theories, if a defendant contractor was shown to have engaged in some fraudulent activity in the procurement of its contractor's license from a state licensing board, relators would be able to argue that every subsequent government contract with the federal government and request for payment was "false," despite the fact that the alleged fraud was wholly disconnected from the defendant's request for payment.

Relators' argument, if accepted, would also raise substantial policy concerns. Were the FCA construed to allow an FCA claim to be based on misrepresentation and omissions made to the FDA during the FDA approval process, the Court sitting on an FCA case would have to delve deeply into

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[4]Liability based solely on cause-in-fact is not typical. Courts have implied limitations, such as requiring proximate cause, even where not expressly imposed by statute. *See Paroline v. United States*, 134 S. Ct. 1710, 1720 (2014). Here, the FCA requires the fraudulent claim be presented "for payment." 31 U.S.C. § 3729(a)(1).

the complexities, subtleties and variabilities of the FDA approval process. Ultimately, to determine materiality under the FCA and the "but-for cause in the chain of causation" analysis advocated by Plaintiff, the Court would have to determine whether the FDA would have in fact approved each drug in question. Given the wide range of administrative responses and action that could have been taken by the FDA (*e.g.*, corrective notices, warnings, plan of remediation, requirement of monitoring), the Court would be tasked not only with determining whether a falsity was presented to the FDA, but also predicting the institutional response of the FDA and the ultimate outcome of a specialized and complex administrative proceeding. Given the range of actions available to the FDA, this would be a daunting task. *Cf. U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd.*, No. 10-11043, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012) ("[T]he FDA has discretion to take a number of different actions should a drug manufacturer violate the adverse-event reporting requirements. The harshest of those actions is the withdrawal of drug approval. However, the FDA exercises discretion in its enforcement procedures for such types of violations, and does not always prosecute them, let alone enforce the harshest penalty available." (citation omitted)); *Zimmerman v. Novartis Pharm. Corp.*, 889 F. Supp. 2d 757, 769 (D. Md. 2012) (noting that the FDA "enforces violations of the drug approval process, not private litigants" and has "a number of enforcement options" including "in rem forfeiture, injunction, and even criminal prosecutions"); *see also Cutler v. Hayes*, 818 F.2d 879, 893 (D.C. Cir. 1987) ("The FDC Act imposes no clear duty upon FDA to bring enforcement proceedings to effectuate either the safety or the efficacy requirements of the Act."). The Court is ill-equipped to make that kind of prediction. Such an inquiry stands in contrast to the inquiry in a more typical FCA case – determining whether a particular statement or certification made to the payor agency is in fact false and material to the decision to pay. Absent a clear directive from Congress, the Court is unwilling to read into the FCA such an expansive sweep.

2. The Implied Certification and Adulteration / Misbranding Theories of Fraud Do Not State an FCA Claim

Relators also allege that implied misrepresentations were in fact made directly to the CMS in seeking reimbursement. In particular, Relators appear to rely on two similar, but distinct, arguments. First, Relators argue that Gilead impliedly certified to CMS compliance with GMP and

safety regulations every time payment for one of the affected drugs was submitted for reimbursement. Second, Relators contend that in selling drugs which under FDA regulations were "adulterated" or "misbranded" drugs,[5] Gilead violated the FCA because the goods sold were not as described.

As to their implied certification argument, Relators rely in large part on the Ninth Circuit's decision in *Ebeid*. Unlike *Eibed*, however, there is no basis for finding any implied certification directed at CMS, the payor agency; payment by CMS was not conditioned on compliance with FDA regulations. All that is required is that the drug in question be approved by the FDA. Relators have cited no Medicare or Medicaid statute, regulation, or contractual term conditioning reimbursement on Gilead's compliance with FDA's safety or GMP regulations.[6] Rather, the only Medicare/Medicaid provision to which Relators cite is the definition of "covered outpatient drug." Under both regimes, a "covered outpatient drug" is, *inter alia*, one "which is approved for safety and effectiveness as a prescription drug" under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.

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[5] A drug can be adulterated for any number of reasons, including contamination in the product; improper controls during manufacturing; or because it differs in strength, quality, or purity from its description in an "official compendium." *See generally* 21 U.S.C. § 351.

[6] Relators have pointed to statements made by Gilead during the FDA approval process in which it certified that it would comply with "all applicable laws" including GMP regulations. For example, at the hearing Relators cited to the 2005 New Drug Application ("NDA") for Gilead's drug "Truvada." At the end of this NDA, as with all NDAs, is a certification box which provides, in relevant part:

> I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. if this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:
>
> 1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.

Docket No. 105-18, at 4 (filed under seal). Relators contend this certification was false when made insofar as the FTC (the active ingredient of Truvada) was not being manufactured pursuant to GMP regulations and was, in fact, adulterated with foreign substances. *See* FAC ¶¶ 105-29. While such statements made during the FDA approval process constitute certifications of regulatory compliance, the certification was not made as part of securing a payment. Relators point to nothing which indicates CMS conditioned payment on such certifications.

§ 355 *et seq.*. 42 U.S.C. § 1396r-8 (medicaid); *see also id.* § 1395w-102(e) (Medicare Part). Here, there is no dispute that the affected drugs at issue in this case were, in fact, "approved" by the FDA.

In addition, for reasons similar to those discussed above, the implied certification theory is problematic when applied to the pharmaceutical context where Congress has established a complex regulatory regime and an executive agency with broad remedial powers to police and enforce that regime. When an "agency has broad powers to enforce its own regulations, as the FDA does . . . , allowing FCA liability based on regulatory non-compliance could 'short-circuit the very remedial process the Government has established to address non-compliance with those regulations.'" *United States ex rel. Rostholder v. Omnicare, Inc,* 745 F.3d 694, 702 (4th Cir. 2014) (quoting *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 307 (3d Cir. 2011)). Violations of, for example, cGMPs would seem better addressed by the FDA regulatory process than by the blunt tool of FCA litigation. Thus, in this healthcare context, courts should be cautious before applying the FCA to claims implicating the FDA's oversight and enforcement powers. *Cf. Wilkins*, 659 F.3d at 307 ("[T]he implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs."); *Mikes*, 274 F.3d at 699 (noting that the implied certification theory should not be read "expansively and out of context" and "does not fit comfortably into the health care context because the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations – but rather only those regulations that are a precondition to payment").

Similarly, any claim that the drugs sold by Gilead and paid for by CMS were adulterated and hence mislabeled is not cognizable under the FCA in this case. This argument has been squarely addressed – and rejected – by the Fourth Circuit in *U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir. 2014). There, the court noted that the Medicare and Medicaid statutes did not require that the sold drugs be unadulterated or misbranded. Rather, the statutes merely defined "covered outpatient drug" (i.e., a drug eligible for reimbursement) as one approved by the FDA .*See id.* at 701 (noting the statutes provide that a "drug merely must be *approved* by the FDA"). Thus, reimbursement requests for drugs that, while approved by the FDA, were subsequently "adulterated"

or "misbranded" as a result of "having been proceeded in violation of FDA safety regulations" would not give rise to FCA liability. *Id.* The court ultimately concluded:

> Here, because compliance with the CGMPs is not required for payment by Medicare and Medicaid, Omnicare has not falsely stated such compliance to the government, as contemplated by the FCA. Thus, relator's allegations of regulatory violations fail to support FCA liability. As we previously have explained, the correction of regulatory problems is a worthy goal, but is "not actionable under the FCA in the absence of actual fraudulent conduct." In the present case, relator has not identified any false statement or other fraudulent misrepresentation that Omnicare made to the government.

Id. at 702.

Omnicare's analysis is persuasive. The FCA is not a "sweeping mechanism to promote regulatory compliance," but rather a "set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct." *Id.*; *see also Lucky v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1045 (N.D. Ill. 1998) ("[T]he FCA is not a vehicle for regulatory compliance."). Further, the Supreme Court has cautioned that the "False Claims Act was not designed to reach every kind of fraud practiced on the Government." *United States v. McNinch*, 356 U.S. 595, 599 (1958). FCA liability cannot be based on fraudulent statements made before one regulatory agency and from that implying a certification putatively made to the payor agency where there is neither an express certification nor condition of payment. To do so would transform the FCA into an all-purpose, anti-fraud statute which it is not. *United States v. AseraCare Inc.*, No. 2:12-CV-245-KOB, 2014 WL 6879254, at *8 (N.D. Ala. Dec. 4, 2014) ("[T]he FCA is not 'an all-purpose antifraud statute.'" (quoting *Allison Engine Co*, 553 U.S. at 672).

To be sure, CMS or the Department of Health and Human Services could require a pharmaceutical manufacturer to certify, for example, its continued adherence to FDA safety and GMP regulations as part of the payment process. *Cf. United States ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296, 297-98, 304 (6th Cir. 1998) (fraudulent deviation from contractually specified requirements for brake shoes violates the FCA). As the Fourth Circuit held in *Omnicare*, however, that is not the case as alleged, and thus no FCA claim has been stated.

2. Relators Have Failed to Allege a Worthless Services Theory

Relators' final FCA theory is a "worthless services" theory. The Ninth Circuit has noted that in an "appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under § 3729, regardless of any false certification conduct." *U.S. ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001). The Second Circuit has similarly noted that such a claim is "effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided. In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all." *Mikes*, 274 F.3d at 703 (citation omitted).

Courts applying this "factually false" or "worthless services" theory have interpreted it narrowly. Most recently, the Seventh Circuit noted that it is "not enough to offer evidence that the defendant provided services that are worth some amount less than the services paid for. That is, a 'diminished value' of services theory does not satisfy this standard. Services that are 'worth less' are not 'worthless.'" *U.S. ex rel. Absher v. Momence Meadows Nursing Center, Inc.*, 764 F.3d 699, 710 (7th Cir. 2014). That court, therefore, rejected the contention that FCA liability could be based simply on the fact that a good or service had a diminished value or was non-conforming in some respect. *See also U.S. ex rel. Ruhe v. Masimo Corp.*, 977 F. Supp. 2d 981, 996 (C.D. Cal. 2013) ("In a worthless services claim involving a medical procedure, the plaintiff must demonstrate that the procedure has 'no medical value.'"). The Seventh Circuit holding is consistent with the worthless services theory articulated by the Ninth Circuit in *U.S. ex rel. Lee* and the Second Circuit in *Mikes*.

In the case at bar, Relators allege a variety of deficiencies in Gilead's pharmaceutical products. Some of these allegations touch on the resulting quality of the drug (as opposed to technical or manufacturing related deficiencies). For example:

- Gilead released "lot 904" of FTC, produced at Synthetics China prior to it being approved by the FDA, for "final drug processing and, ultimately, commercial sale" despite the presence of microbial contamination – including molds and yeasts beyond established limits and two micro-organisms. FAC ¶¶ 57.

- FTC and finished Truvada tablet cores were produced and released for processing that contained the "cyclic FTU"

impurity, manifested in the form of charred and degraded particles. *Id.* ¶¶ 110, 113.

- FTC "Lot 5044" was "both visually contaminated and failed potency and purity testing, but was nevertheless utilized in commercially distributed drug product." *Id.* ¶ 124. Lot 5044 tested at "94.8% potency" when acceptable limited were "98.0-102.0%." *Id.* ¶ 125.

- Validation lots from Synthetic China's "Plant 203" were released for commercial sale despite the presence of foreign particles including "blue colored glass, cement and fibrous materials, and metal shards," with the largest piece weighing 39mg – "7.8% by weight of a Truvada tablet, or up to 19.5% of an Emtriva capsule." *Id.* ¶ 160.

- Validation lots of Viread tablets were released into the commercial market despite the presence of "visible black particles" – eventually discovered to be "teflon, charred TDF, acetaminophen, metal shavings, and other materials" – in numerous batches. *Id.* ¶¶ 180, 184. 185.

- Various products were subject to temperature extremes resulting in "scores of complaints about broken, moist, melted, and/or fused drug products, as well as noticeable odors." *Id.* ¶ 213.

These allegations, and similar allegations throughout the FAC, while troubling, do not establish that the affected lots or products were not only "worth less" or defective, but truly "worthless" for the purposes for which the drugs were designed. *See Momence Meadows*, 764 F.3d at 710. Notably, the United States, in its statement of interest, appears to recognize that the drug at issue would need to be "worthless" in some sense: "Further, in some situations, manufacturing deficiencies violating GMP regulations could affect the strength, purity, and/or quality of the affected drug such that the drug is essentially 'worthless' and not eligible for payment by the government." Dkt. No. 78, at 3. Here, however, Relators have failed to allege sufficient facts to state a claim under the narrow "worthless services" theory.[7]

[7]The limitations of the "worthless services" doctrine do not prevent an FCA claim for the sale of non-conforming goods to the government where, for example, there is a knowing breach of a material specification established by contract with the payor agency. *See, e.g.*, *Compton* 142 F.3d at 304.

3. Conclusion

For the foregoing reasons, Relators' FCA claim is dismissed. However, the Court cannot say at this early stage that any amendment by Relators would be futile. Accordingly, Relators will be afforded an opportunity to allege either (1) requests for reimbursement for "worthless services" or (2) an actionable misrepresentation made as part of the payment process consistent with the analysis above . Should Relators seek to file an amended complaint, the Court expects the Relators to organize and streamline the current 747 paragraph, 190 page complaint in light of the above analysis.

C. Relators' FCA Conspiracy Claim Is Barred by the Intracorporate Conspiracy Doctrine

Relators' third claim for relief asserts a conspiracy to violate the False Claims Act in violation of 31 U.S.C. § 3729(a)(1)(C). This provision creates liability for any person who "conspires to commit a violation" of the FCA. Gilead moves to dismiss this claim, arguing that, as a matter of law, Gilead Alberta ULC and Gilead Sciences, Inc. cannot conspire together because the former is a wholly owned subsidiary of the latter. Docket No. 58, at 25; *see also* Docket No. 57 (Defendants' Certification of Interested Entities) ("Gilead Alberta ULC makes the following disclosure: it is a wholly-owned subsidiary of Gilead Alberta LLC, which is a wholly-owned subsidiary of Gilead Sciences, Inc.").

Gilead's argument relies on the intra-corporate conspiracy doctrine – an antitrust principle – which "provides that, as a matter of law, a corporation cannot conspire with its own employees or agents." *Hoefer v. Fluor Daniel, Inc.*, 92 F. Supp. 2d 1055, 1057 (C.D. Cal. 2000). The reasoning behind this doctrine is that "it is not possible for a single legal entity consisting of the corporation and its agents to conspire with itself, just as it is not possible for an individual person to conspire with himself." *Microsoft Corp. v. Big boy Distribution LLC*, 589 F. Supp. 2d 1308, 1322 (S.D. Fla. 2008). Courts have used this principle to bar conspiracy claims where the purported conspirators were a parent corporation and a wholly-owned subsidiary. *See, e.g., United States v. Medco Health Systems, Inc.*, No. 12-522 (NLH) (AMD), 2014 WL 4798637, at *11 (D.N.J. Sept. 26, 2014) ("The intra-corporate conspiracy doctrine, raised by defendants, contemplates the ramifications of this type of parent/subsidiary relationship. The doctrine provides that a wholly

owned subsidiary is deemed incapable of conspiring with its parent company, and it has long been applied to conspiracy claims generally.").

Relators contend that this doctrine does not extend beyond the confines of the Sherman Antitrust Act, noting that the Supreme Court has stated that "antitrust law's intracorporate conspiracy doctrine . . . turns on specific antitrust objectives." *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 166 (2001). However, courts have not construed the intra-corporate conspiracy doctrine as narrowly as Relators contend and a number of courts have applied it in FCA cases. *See, e.g.*, *United States ex rel. Chilcott v. KBR, Inc.*, No. 09-cv-4018, 2013 WL 5781660 (C.D. Ill. Oct. 25, 2013) ("[T]he Court holds that the intracorporate conspiracy doctrine bars FCA conspiracy claims where all the alleged conspirators are either employees or wholly-owned subsidiaries of the same corporation."); *United States ex rel. Ruhe v. Masimo Corp.*, 929 F. Supp. 2d 1033, 1038 (C.D. Cal. 2012) ("Contrary to Relators' assertion, this doctrine applies to conspiracy claims outside of antitrust, where it was originally developed, and has in fact been applied by several federal courts to claims under the FCA."); *United States ex rel. Fago v. M & T Mortgage Corp.*, 518 F. Supp. 2d 108, 117-18 (D.D.C. 2007) (applying the doctrine in the FCA context). Relators point to no authorities rejecting application of the doctrine in the FCA context.

Accordingly, in addition to the failure to state a substantive FCA claim, the intracorporate conspiracy doctrine requires that Gilead's motion to dismiss Relators' conspiracy claim under the FCA be **GRANTED**.

D. Relators' FCA and FLSA Retaliation Claims

Relators' twenty-eighth and thirty-second causes of action allege that Relator Jeff Campie was retaliated against in violation of the FCA and Fair Labor Standards Act ("FLSA"), respectively. Mr. Campie alleges that beginning "in or about July 2006, and throughout his employment with Gilead, Relator spoke to Gilead's top executives . . . on numerous occasions about concerns he had with and objections to the manufacturing and compliance related practices" alleged in the FAC. FAC ¶ 680. He then contends that Gilead executives engaged in "ongoing retaliation toward him, including, but not limited to, ostracizing Relator Jeff Campie, threatening to terminate his employment in approximately mid-January 2009, and ultimately terminating his employment in July

2009." *Id.* ¶ 681. Mr. Campie asserts that this retaliation was caused by "his opposition and objections to Gilead's unlawful practices." *Id.* ¶ 685.

The FCA contains an anti-retaliation provision which provides:

> Any employee . . . shall be entitled to all relief necessary to make that employee . . . whole, if that employee . . . is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee . . . in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. § 3730(h). To state a claim for retaliation under the FCA, a plaintiff must demonstrate: (1) that he or she "engaged in activity protected under the statute"; (2) that the employer knew the plaintiff engaged in protected activity; and (3) the employer discriminated against the plaintiff "because he or she engaged in protected activity." *Mendiondo v. Centinela Hosp. Medical Center*, 521 F.3d 1097, 1103 (9th Cir. 2008). An employee engages in protected activity by "'investigating matters which are calculated or reasonably could lead to a viable FCA action.'" *Moore v. Cal. Institute of Tech. Jet Propulsion Lab.*, 275 F.3d 838, 845 (9th Cir. 2002) (quoting *Anton*, 91 F.3d 1269). Protected activity includes situations where: "(1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is possibly committing a fraud against the government." *Moore v. Cal. Institute of Tech. Jet Propulsion Lab.*, 275 F.3d 838, 845 (9th Cir. 2002).

The FLSA makes it unlawful for an employer to

> discharge or in any other manner discriminate any employee because such employee has filed any complaint or caused to be instituted any proceeding under or related to this chapter, or has testified or is about to testify in any such proceeding, or has served or is about to serve on an industry committee;

29 U.S.C. § 215(a)(3). Under this provision, a plaintiff must demonstrate: "(1) the plaintiff must have engaged in statutorily protected conduct under § 5(a)(3) of the FLSA, or the employer must have erroneously believed that the plaintiff engaged in such conduct; (2) the plaintiff must have suffered some adverse employment action; and (3) a causal link must exist between the plaintiff's conduct and the employment action." *Singh v. Jutla & C.D. & R's Oil, Inc.*, 214 F. Supp. 2d 1056, 1059 (N.D. Cal. 2012).

Mr. Campie's retaliation claims fail at this stage for the simple reason that there are insufficient allegations from which it can be inferred that any adverse employment action he suffered was caused by his engaging in protected activity under the FCA or FLSA.[8] Mr. Campie contends that he has sufficiently alleged causation because, in two paragraphs (out of a complaint consisting of 747 paragraphs), he alleged that he "worked for Gilead from 2006 through mid-2009 before his employment was terminated as a result of raising objections to Gilead's conduct." FAC ¶ 5; *see also* Dkt. No. 84, at 32 ("Finally, Relators have also sufficiently alleged that Mr. Campie suffered adverse action because he engaged in protected conduct." (citing FAC ¶¶ 5, 691)). These are, however, conclusory allegations without any factual support. Similar conclusory allegations regarding causation can be found elsewhere in the FAC. *See, e.g.*, *id.* ¶ 681 ("On an ongoing basis Relator Jeff Campie raised concerns . . . and in response to his having raised such concerns and objections, Caracciolo and Branning, among others at Gilead, engaged in ongoing retaliation toward him . . . .").

These statements fail to provide sufficient *factual* allegations from which it can be inferred that Mr. Campie was subjected to an adverse employment action *because of* his protected activity. *See U.S. ex. rel. Patton v. Shaw Services, LLC*, 418 F. App'x 366, 372 (5th Cir. 2011) ("Patton's allegations that Shaw supervisors retaliated against him for internally reporting 'fraudulent' construction practices . . . are conclusory and unsupported by specific facts creating a genuine issue for trial."); *Beers v. Kaiser Permanente Northeast Div.*, No. 98-CV-1121 (TJM), 1999 WL 1269419, at *4 (N.D.N.Y. Dec. 16, 1999) ("The alleged temporal proximity between Plaintiff's complaints and termination and Plaintiff's conclusory statements that she was terminated because she complained 'early and often' of violations are insufficient to establish the necessary inference." (citation omitted)). Mr. Campie need not provide extensive factual support on this point. *See Mendiondo*, 521 F.3d at 1104 ("It suffices at this pleading stage for Mendiondo to simply give

[8] Gilead argues that the FAC contains insufficient allegations that Mr. Campie did, in fact, engage in protected conduct. Insofar as Mr. Campie has indicated that he can provide further factual allegations on this point and he will need to amend his retaliation claims for the reason articulated in this order, the Court declines to address this argument until Mr. Campie has had an opportunity to include all pertinent factual allegations in an amended complaint.

notice that she believes CHMC terminated her because of her investigation into the practices she specified in the complaint.").

Here, it appears that Mr. Campie relies on a number of vague allegations and the alleged temporal proximity between his protected conduct and his termination to infer retaliatory intent. For example, he alleges that, at some undisclosed time, he informed Gilead management that it would be "illegal to market" certain drugs from an unregistered facility. FAC ¶ 79. He maintains that he was "rebuked for the warnings by Tony Caracciolo, Gilead's Senior Vice President for Manufacturing and Operations." *Id.* Similarly, in 2008, when Mr. Campie requested that a customer complaint be sent for analysis he was "critiqued" by his manager and that his manager "reprimanded Mr. Campie for relaying to Gilead management that the commingling incident was a recallable event, stating that this evidenced that Mr. Campie was of little use to the company and that Mr. Campie's 'heart wasn't in the job anymore.'" *Id.* ¶ 230, 232. Vague allegations of Mr. Campie being "critiqued" at some unspecified date or "reprimanded" a year before his termination are insufficient to give rise to an inference that his termination was the result of protected activity.

Further, in a variety of employment law contexts, courts have been wary about implying causation solely based on temporal proximity where that proximity is not particularly convincing. *See, e.g.*, *Vasquez v. County of Los Angeles*, 349 F.3d 634, 646 (9th Cir. 2003) (finding no causal link where "the protected activity occurred thirteen months prior to the alleged adverse action" and the plaintiff failed to provide other "evidence of surrounding circumstances that show a retaliatory motive"); *Caprio v. Mineta*, No. CIVA 04-5805 MLC, 2007 WL 2885815, at *9 (D.N.J. Sept. 27, 2007) ("Temporal proximity between the protected activity and allegedly retaliatory conduct may be relevant, but hte temporal proximity here is not unusually suggestive, and timing alone is rarely sufficient to establish causation."). Here, the temporal connection is not very strong because Mr. Campie merely alleges that he made "ongoing complaints" (beginning in July 2006) and that he was eventually terminated in 2009, three years later.

For the foregoing reasons, Mr. Campie's retaliation claims under the FCA and FLSA will be **DISMISSED** with leave to amend. In his amended complaint, Mr. Campie must allege sufficient

factual allegations from which it can be inferred that Gilead terminated him as a result of his protected activity under the FCA and FLSA.

E. The Court Defers Addressing Relators' State Law Claims

Having dismissed Relators' FCA claim and Mr. Campie's retaliation claims under the FLSA and FCA (the latter with leave to amend), the only remaining claims are brought under state law. The Court defers ruling on these claims pending Relators' amendment to their complaint and proper briefing on the remaining state law claims.[9]

IV. CONCLUSION

For the foregoing reasons, Relators' federal False Claims Act cause of action is dismissed. As discussed above, Relators will be afforded leave to amend this claim. Further, this dismissal is without prejudice to the United States. *See, e.g., U.S. ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005); *U.S. ex rel. Shea v. Verizon Bus. Network Servs. Inc.*, 904 F. Supp. 2d 28, 37 (D.D.C. 2012). Mr. Campie's retaliation claims under the FCA and FLSA are also dismissed with leave to amend.

The amended complaint shall be filed by **Monday, February 9, 2015** at **5:00pm**. Insofar as the federal claims in this case remain unsettled, the Court defers consideration of Relators' state law claims.

This order disposes of Docket No. 58.

IT IS SO ORDERED.

Dated: January 7, 2015

EDWARD M. CHEN
United States District Judge

[9] The Court notes that Gilead moved to dismiss the various state law false claims act causes of action in a five sentence paragraph that failed to cite relevant case law from all of the affected states or otherwise attempted to support its contention that the state law claims should rise or fall with the federal claim. Gilead is advised, for purposes of any further proceeding, that the Court does not consider such a conclusory argument sufficient to actually present a ground for dismissing a cause of action.